UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

IN RE LUMIFY	Civil Action No. 21-16766 (RK) (RLS) (CONSOLIDATED) *Document Electronically Filed*

PLAINTIFFS' RESPONSIVE *MARKMAN* BRIEF

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I. INTRODUCTION

Defendants' opening claim construction brief (ECF No. 136) improperly ignores vital intrinsic evidence, including the '600 patent specification and prosecution history, which critically illuminate the meaning of the claim phrases to one of skill in the art. Contrary to Defendants' arguments, Plaintiffs' opening claim construction brief (ECF No. 152) properly identified the plain and ordinary meaning of the disputed claim phrases in light of the specification and prosecution history, without reading elements into the claim from the specification. Accordingly, and as discussed further below, Plaintiffs respectfully request that the Court reject Defendants' proposed claim constructions and adopt Plaintiffs' proposed constructions.

With respect to the claim phrase "[human] in need of said reduction of eye redness," Defendants fail to properly consider the specification, which is replete with references to the usage of brimonidine to achieve significantly reduced ocular hyperemia via vasoconstriction as a key component of the invention. *See, e.g.*, Ex. 1[1] ('600 patent), 2:51-55. And indeed, the prosecution history aligns with the specification in this regard. Ex. 17 ('600 patent file history, November 4, 2022 Response to Office Action) at 7, 11-12, 14-15. Similarly, with regard to the claim phrase "as the sole active ingredient," Defendants wholly ignore the prosecution history evidencing Patentee's clear disavowal of administering any other active ingredients as part of the dosing protocol with brimonidine—instead seeking to impermissibly broaden the phrase to encompass disclaimed subject matter. *See, e.g.*, *id.* at 13. Plaintiffs' proper constructions of the claim phrases in light of the intrinsic evidence adhere to established Federal Circuit precedent and legal principles that Defendants readily acknowledge in their own brief (ECF No. 136 at 7-8), and Plaintiffs'

[1] Exhibits 1-18 are attached to the Declaration of Bryan C. Diner in Support of Plaintiffs' Opening *Markman* Brief (ECF No. 152-1), and Exhibit 19 is attached to the accompanying Supplemental Declaration of Bryan C. Diner in Support of Plaintiffs' Responsive *Markman* Brief.

constructions in no way amount to a "cardinal sin" (ECF No. 136 at 10). By contrast, Defendants' disregard of the intrinsic record clearly violates fundamental claim construction principles. *Phillips v. AWH Corp.*, 415 F.3d 1303, 1313-17 (Fed. Cir. 2005) (en banc) ("Importantly, the person of ordinary skill in the art is deemed to read the claim term not only in the context of the particular claim in which the disputed term appears, but in the context of the entire patent, including the specification."); *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996) (finding intrinsic evidence such as the prosecution history to be "the most significant source of the legally operative meaning of disputed claim language").

For these reasons and as discussed further below, Plaintiffs respectfully request that the Court adopt Plaintiffs' proposed constructions and reject Defendants' constructions.

II. ARGUMENT

Defendants' proposed constructions are untethered to the intrinsic record and contrary to the plain and ordinary meaning of the disputed claim phrases. Defendants selectively ignore important portions of the intrinsic record that contravene their proposals, in violation of established Federal Circuit precedent and the legal standards set forth in Defendants' own brief. *See, e.g.*, ECF No. 136 at 7-8. As a result, Defendants' proposed constructions are inconsistent with the nature and purpose of the claimed subject matter in light of the specification and prosecution history. In contrast, Plaintiffs propose that the claim terms and phrases disputed by Defendants be construed according to their plain and ordinary meaning, including in light of the specification and prosecution history. Plaintiffs' proposed constructions—unlike Defendants'—are consistent with the intrinsic record as a whole.

A. The Court Should Adopt Plaintiffs' Proposed Construction of the Claim Phrase "[human] in need of said reduction of eye redness"[2]

The parties dispute whether claim 1 of the '600 patent, through the phrase "[human] in need of said reduction of eye redness," requires that that hyperemia in the human subject is reduced by vasoconstriction. Plaintiffs submit that it does—as confirmed by ***all*** of the intrinsic evidence, which Defendants largely ignore. Defendants ignore, for example, that their construction of the phrase-at-issue would render it redundant of other claim language—an approach that is presumptively incorrect. ECF No. 152 at 19-20. Defendants also neglect that the phrase-at-issue appears in the context the claimed method "for reducing eye redness," which the specification repeatedly attributes to vasoconstriction— describing that "[o]ne of the key discoveries of the present invention lies in using low doses of [brimonidine] to achieve vasoconstriction with significantly reduced hyperemia." *Id.* at 18; Ex. 1 ('600 patent), 2:51-55. Defendants further disregard entirely the prosecution history of the '600 patent, where the patentee repeatedly characterized the claimed invention as "affirmatively reduc[ing] eye redness"—attributable to vasoconstriction—in order to distinguish a reference that Defendants apparently seek to reinvigorate. *Id.* at 18-19. Defendants have thus failed to interpret the phrase "[human] in need of said reduction of eye redness" in full view of the intrinsic evidence, as required under *Phillips v. AWH Corp.*, 415 F.3d 1303 (Fed. Cir. 2005). As such, Defendants' duplicative and self-serving proposed construction warrants rejection.

[2] The parties agree that "in need of said reduction of eye redness" refers to a human "having ocular hyperemia." *See* ECF No. 136 at 5.

1. Plaintiffs' Proposed Construction Properly Interprets the Claim Phrase in Light of the '600 Patent Specification, While Defendants' Proposed Construction Ignores the Specification in Violation of Federal Circuit Precedent

Defendants candidly acknowledge that patent claims must be read in view of the specification. *See* ECF No. 136 at 7 (quoting *Phillips*, 415 F.3d at 1315 (claims "must 'be read in view of the specification, of which they are part'" as "it is the single best guide to the meaning of a disputed term")). Defendants nevertheless assert that Plaintiffs' construction of the claim phrase "in need of said reduction of eye redness" should be rejected because it allegedly requires committing "one of the cardinal sins of patent law" by "reading a limitation from the written description into the claims." ECF No. 136 at 10-11. Defendants are wrong and their argument should be rejected.

At the outset, Defendants' reliance on *SciMed Life Sys., Inc. v. Advanced Cardiovascular Sys., Inc.*, 242 F.3d 1337 (Fed. Cir. 2001) is flawed, as a proper reading of *SciMed* actually reinforces Plaintiffs' construction, which interprets the phrase-at-issue ***in light of*** the specification. In *SciMed*, the district court construed a claim based on the specification because the express language of the specification "leaves no doubt that a person skilled in the art would conclude that the inventor envisioned only one [structure]" for practicing the invention. *Id*. at 1339-40. On appeal, the Federal Circuit rejected an argument that the district court had committed a "cardinal sin" in its construction as "***not*** an accurate characterization." *Id.* at 1340. "Instead, the district court properly followed the invocation that '***[c]laims must be read in view of the specification***, of which they are a part.'" *Id.* at 1340–41 (emphasis added). Thus, the *SciMed* Court, as well as numerous other Courts in similar cases, clearly distinguished between reading a limitation from the specification *into* the claims and properly reading the claims *in light of* the specification—validating the latter, consistent with Plaintiffs' construction here. *SciMed*, 242 F. 3d at 1341-42

(collecting cases); *see Alloc, Inc. v. Int'l Trade Comm'n*, 342 F.3d 1361, 1370 (Fed. Cir. 2003) ("[W]here the specification makes clear at various points that the claimed invention is narrower than the claim language might imply, it is entirely permissible and proper to limit the claims."); *Carrum Techs., LLC v. Unified Pats., LLC*, No. 2020-2204, 2021 WL 3574209, at *5-6 (Fed. Cir. Aug. 13, 2021) (rejecting a "broad reading" of the claim phrase at issue that was "untethered to the specification" in favor of "the phrase's ordinary and customary meaning, as understood by a skilled artisan when read in the context of the specification").

As in *SciMed*, the '600 patent specification contains repeated and express language that "leaves no doubt" to a person skilled in the art that the claimed invention must be understood as using brimonidine to achieve significantly reduced ocular hyperemia with more effective vasoconstriction. *SciMed*, 242 F.3d at 1339. Indeed, there are no less than 60 references to redness reduction via vasoconstriction throughout the specification. *See, e.g.*, Ex. 1 ('600 patent), 2:51-56, 4:40-54, 5:51-56, 13:30-33, 14:33-36. No other means of reducing eye redness is described, supporting an "inescapable conclusion" by a person of ordinary skill in the art that achieving redness reduction by vasoconstriction is an essential feature of the patented invention. *SciMed*, 242 F.3d at 1342.

Defendants' reliance on *Comark Communications, Inc. v. Harris Corp.*, 156 F.3d 1182 (Fed. Cir. 1998) is likewise unavailing. ECF No. 136 at 10-11. The Court in *Comark* emphasized that the skilled artisan should "look[] to the specification to ascertain the meaning of a claim term as it is used by the inventor in the context of the entirety of his invention" where a proposed construction in that case merely described how the claim term was to be used in a single embodiment of the invention without "shed[ding] light" on the meaning of the term more generally. *Id.* at 1187. By contrast, the '600 patent specification makes abundantly clear that the

reduction of hyperemia by vasoconstriction is a key component of the invention throughout multiple embodiments in the specification. *See, e.g.*, Ex. 1 ('600 patent), 2:35-39, 51-56, 59-63, 4:40-45, 13:28-33. Thus, Plaintiffs' construction properly relies on guidance from the specification to "shed light" on the meaning of the claim phrase to a person of ordinary skill in the art. Defendants' proposed construction (i.e., "having ocular hyperemia"), on the other hand, is merely duplicative of the claim preamble (i.e., "a method . . . in a human subject **having ocular hyperemia**") (emphasis added), and hence should be rejected because it "in no way sheds light on either the meaning of the [phrase] to the inventor, or the common meaning of the term to one of skill in the art." *Comark* 156 F.3d at 1187.

In short, far from reading a limitation from the specification *into* the claims, Plaintiffs' construction of "a human having ocular hyperemia, where such hyperemia is reduced by vasoconstriction" properly reads the claim *in light of* the specification, consistent with the direction provided by the Federal Circuit in *Phillips* and its progeny. *See, e.g.*, *In re Suitco Surface, Inc.*, 603 F.3d 1255, 1260 (Fed. Cir. 2010) ("[C]laims should always be read in light of the specification and teachings in the underlying patent."); *In re Abbott Diabetes Care Inc.*, 696 F.3d 1142, 1149 (Fed. Cir. 2012); *KEYnetik, Inc. v. Samsung Elecs. Co.*, 837 F. App'x 786, 791–92 (Fed. Cir. 2020).

2. Defendants' Proposed Construction Selectively Ignores Vital Portions of the Intrinsic Record Including the '600 Patent Prosecution History

Defendants also improperly ignore another important component of the intrinsic evidence that further supports Plaintiffs' proposed construction—namely, the '600 patent prosecution history. *Carrum Techs.*, 2021 WL 3574209, at *4 ("Under the *Phillips* standard, claim terms are generally given their ordinary and customary meaning as understood by a skilled artisan when read in the context of the specification and prosecution history."); *Cordis Corp. v. Bos. Scientific Corp.*, 658 F.3d 1347, 1356 (Fed. Cir. 2011) ("Claim terms must be construed in light of all of the intrinsic

evidence, which includes not only the claim language and patent written description, but also the prosecution history."); *see Phillips* 415 F.3d at 1317 (explaining that the prosecution history "can often inform the meaning of the claim language"). During the '600 patent prosecution, the Patentee specifically amended the claims to recite the limitation of redness reduction by vasoconstriction in order to distinguish from the prior art and repeatedly emphasized that the claimed method requires **achieving** redness reduction. ECF No. 152 at 12-13; Ex. 17 ('600 patent file history, November 4, 2022 Response to Office Action) at 7, 13 (emphasis added). These repeated statements relating to affirmative reduction of ocular hyperemia throughout the '600 patent prosecution history, which were vital to distinguish from the prior art, are consistent with Plaintiffs' construction, and support the fact that actual reduction of ocular hyperemia is an indispensable part of the patented methods.

3. Defendants Incorrectly Assert that Plaintiffs Seek to Read an Efficacy Limitation Into the Claims, Where the Claims, Read in Light of the Intrinsic Record, Naturally Require An Efficacy Limitation.

Defendants further assert that Plaintiffs seek to "add a requirement that the treatment is efficacious." ECF No. 136 at 11. Defendants are wrong. Here again, Defendants simply ignore the weight of the intrinsic evidence based on the specification and the prosecution history (*see supra* § II.A.1-2), which naturally illustrate that the claimed methods actually reduce ocular hyperemia by vasoconstriction.

Defendants' cited cases (ECF No. 136 at 11-12) are inapposite when considered in the context of these disclosures. Each involved an attempt to introduce an efficacy standard into the claim that was not adequately supported by the intrinsic evidence. *See Aventis Pharma S.A. v. Hospira, Inc.*, 675 F.3d 1324, 1330 (Fed. Cir. 2012) ("**[n]either the claims, the specification, nor the prosecution history** suggest that the claimed perfusion must satisfy certain safety or efficacy standards") (emphasis added); *Mitsubishi Chem. Corp. v. Barr Lab'ys, Inc.*, 435 Fed. App'x 927, 934–35 (Fed. Cir. 2011) (declining to limit a claim to only compounds that are "safe, effective,

and reliable for use in humans" because there was **no support for such a limitation in the specification** and the property is not "necessary for patentability") (emphasis added); *Iovate Health Scis., Inc. v. Bio-Engineered Supplements & Nutrition, Inc.*, 586 F.3d 1376, 1381-82 (Fed. Cir. 2009) (refusing to read an effectiveness requirement into the preamble of a claim when there is no evidence in the patent specification); *Celgene Corp. v. Hetero Labs Ltd.*, 17-cv-3387, 2020 WL 3249117, at *5 (D.N.J. June 16, 2020) (declining to read an efficacy requirement into the term "treating multiple myeloma" where "**nothing in the claim language, the specification, or the prosecution history** warrants reading into the claim an efficacy limitation based on the preamble") (emphases added). By contrast, there is abundant support throughout the specification and the prosecution history of the '600 patent indicating that the claimed methods for reducing eye redness in a human subject having ocular hyperemia that is "in need to said reduction to eye redness" are methods that use vasoconstriction to achieve this purpose. *See, e.g.*, Ex. 1 ('600 patent), 2:43-55; 4:40-54, 4:62-5:6, Examples 1, 4, and 5; Ex. 17 ('600 patent file history, November 4, 2022 Response to Office Action) at 2, 7.

Wholly separate and apart from what the intrinsic evidence dictates about actual redness reduction, Defendants' position that the claimed method is limited to reducing eye redness but does not require any redness reduction makes no sense. The preamble is written in the gerund form of the verb—*reducing* eye redness. It requires reduction of redness just as the step of administrating brimonidine, also written in the gerund form of the verb ("administering"), requires brimonidine to be actually administered to practice the claim. As no one would credibly argue that there is no requirement that brimonidine actually be administered, nor can it be credibly argued a reduction in redness is not needed to practice the claimed method of *reducing* eye redness. *Sanofi Mature IP v. Mylan Lab'ys Ltd.*, 757 F. App'x 988, 933 (Fed. Cir. 2019) (holding that claimed preamble of

"[a] method of increasing survival" when read with claim language directed to a person in need thereof required increasing survival to practice the claimed method).

For these reasons, and those discussed in Plaintiffs' opening brief, Plaintiffs respectfully request that the Court reject Defendants' construction and adopt Plaintiffs proposed claim construction for this disputed phrase.

B. The Court Should Adopt Plaintiffs' Proposed Construction of the Phrase "as the sole active ingredient"

1. Defendants' Construction Directly Contradicts Intrinsic Evidence that Properly Requires Brimonidine as the Only Active Ingredient and Would Improperly Encompass Disclaimed Subject Matter

The parties dispute whether the phrase "[administering brimonidine] as the sole active ingredient" encompasses use of a different active ingredient in a separate ocular drop (or otherwise). Plaintiffs submit that it does not, and thus it should be construed as "[administering brimonidine] as the only active ingredient to affirmatively reduce redness in a person having ocular hyperemia." Defendants criticize Plaintiffs' construction because "the entire method is now restricted to just brimonidine as the 'only active ingredient to affirmatively reduce redness in a person having ocular hyperemia.'" ECF No. 136 at 15. But this is exactly what the Patentee intended as reflected in the prosecution history, which Defendants again improperly ignore. *See Phillips*, 415 F.3d at 1317 ("[T]he prosecution history can often inform the meaning of the claim language by demonstrating . . . whether the inventor limited the invention in the course of prosecution, making the claim scope narrower than it otherwise would be.") (citations omitted); *Chimie v. PPG Indus., Inc.*, 402 F.3d 1371, 1384 (Fed. Cir. 2005) (using the prosecution history to "exclude any interpretation that was disclaimed during prosecution") (citations omitted).

During prosecution, the Patentee clearly and unmistakably disclaimed administering brimonidine with any other active ingredient in the claimed method. *See* ECF No. 152 at 22-24.

Confronted with the Dean reference, which discloses use of brimonidine and another active ingredient as part of the same dosage protocol for treating conditions other than ocular hyperemia, the Patentee distinguished Dean because it does not disclose using brimonidine "as the sole active ingredient," much less to "affirmatively reduce eye redness in a patient having ocular hyperemia." Ex. 17 ('600 patent file history, November 4, 2022 Response to Office Action) at 12. Instead, as the Patentee explained, Dean "is directed to ***combinations*** of brinzolamide and brimonidine." *Id.* at 12 (emphasis added); *see* Ex. 10 (Dean) at 2:55-57 ("When two separate formulations of brinzolamide and brimonidine are used, the preferred administration sequence is brimonidine first and brinzolamide second."). The '600 patent was allowed based on this distinction. Ex. 18 ('600 patent file history, December 1, 2022 Office Action) at 2-3. It necessarily follows that the claims of the '600 patent do not encompass use of another active ingredient beyond brimonidine, including in a separate ocular drop as Defendants have proposed. *See MBO Lab'ys, Inc. v. Becton, Dickinson & Co.*, 474 F.3d 1323, 1330 (Fed. Cir. 2007) ("Prosecution arguments like this one which draw distinctions between the patented invention and the prior art are useful for determining whether the patentee intended to surrender territory, since they indicate in the inventor's own words what the invention is not."); *N. Am. Container, Inc. v. Plastipak Packaging, Inc.*, 415 F.3d 1335, 1345-46 (Fed. Cir. 2005) (affirming disclaimer as the "inescapable consequence" of an argument made by the patentee to overcome an obviousness rejection "during prosecution to gain allowance for his claims"); *see also Cordis Corp.*, 658 F.3d at 1356-57 (relying on distinction over prior art reference during prosecution to support narrow claim construction and confirming scope of the disclaimer based on the contents of that prior art reference); *CIAS, Inc. v. Alliance Gaming Corp.*, 504 F.3d 1356, 1363 (Fed. Cir. 2007) ("Although the usage 'comprised of' does not itself exclude the presence of additional elements or steps, this does not permit recovery of claim scope that was

limited during prosecution."). .Misinterpreting the claim language, Defendants contend that brimonidine need only be the sole active ingredient in the ocular drop because the claim allegedly "is agnostic" as to whether other drugs could be administered as part of the treatment. ECF No. 136 at 14. But the Patentee's statements during prosecution control and preclude Defendants' interpretation of the disputed phrase. *Omega Eng'g, Inc. v. Raytek Corp.*, 334 F.3d 1314, 1324 (Fed. Cir. 2003) ("[W]here the patentee has unequivocally disavowed a certain meaning to obtain his patent, the doctrine of prosecution disclaimer attaches and narrows the ordinary meaning of the claim congruent with the scope of the surrender."). As such, Defendants' construction should be rejected.

2. Defendants' Other Arguments Are Unavailing

Defendants follow their deficient analysis of the meaning of "as the sole active ingredient" with additional arguments that, in their view, allegedly support their proposed construction. ECF No. 136 at 14-16. But these arguments are disingenuous, as best. And, as explained below, each is incorrect.

For example, Defendants assert that Plaintiffs' construction "renders meaningless the express limitation that the ocular drop contains brimonidine as the sole active ingredient." *Id.* at 15. Not so. Under Plaintiffs' construction, when properly read in the context of the claim as a whole, brimonidine still must be the "sole active ingredient" in the ocular drop.[3] And consistent with the clear and unmistakable disclaimer during prosecution, Plaintiffs' construction excludes topically administering any other active ingredients with brimonidine—by a separate ocular drop or otherwise. Thus, Plaintiffs' construction does not "ignore[]" the claim language, as Defendants wrongly suggest. *Id.*

[3] Defendants' claim that Plaintiffs' construction would render "the entire claim incoherent" (*id.* at 14) ignores that the bracketed text ("[administering brimonidine]") is provided solely for context.

Defendants also feign ignorance by asserting that Plaintiffs' construction would improperly introduce an allegedly "indefinite" definition "to affirmatively reduce redness" into the claim. ECF No. at 15-16. Defendants again are incorrect. The Patent Examiner had no trouble understanding the meaning of this definition during prosecution, when the Patentee distinguished Dean for its failure to teach "using brimonidine . . . as the sole active ingredient to affirmatively reduce eye redness . . . ." Ex. 17 ('600 patent file history, November 4, 2022 Response to Office Action) at 12. Based on that exchange, a person of ordinary skill in the art would have readily understood that the method does not read on topically administering any other drugs with brimonidine, without regard their ability to reduce redness. Stated plainly, brimonidine is the ***sole active ingredient*** used in the claimed method. The meaning of "to affirmatively reduce eye redness" would have been understood, consistent with the specification, to refer to achieving a reduction in eye redness, eliminating any purported "indefiniteness" concerns. Ex. 1 ('600 patent), 2:51-55, Examples 1, 4, 5; *see Bancorp Servs., L.L.C. v. Hartford Life Ins. Co.*, 359 F.3d 1367, 1373 (Fed. Cir. 2004) ("The failure to define the term is, of course, not fatal, for if the meaning of the term is fairly inferable from the patent, an express definition is not necessary"); Ex.19 (Supplementary Examination Guidelines for Determining Compliance With 35 U.S.C. 112 and for Treatment of Related Issues in Patent Applications, February 9, 2011) at 7166 ("To meet the definiteness requirement under § 112… the exact claim terms are not required to be used in the specification as long as the specification provides the needed guidance on the meaning of the terms (e.g., by using clearly equivalent terms) so that the meaning of the terms is readily discernable to a person of ordinary skill in the art.").

C. Defendants' Improper Use of Claim Construction to Argue Invalidity

In their opening claim construction brief, Defendants made numerous conclusory and improper statements such as "The '600 Patent is Directed to the Use of an Obvious Concentration

of Brimonidine Tartrate to Treat eye Redness." ECF No. 136 at 2-4. Defendants' statements amount an impermissible attempt to improperly argue invalidity in a claim construction brief. *See Nobelbiz, Inc. v. Global Connect, L.L.C.*, 876 F.3d 1326, 1328 (Fed. Cir. 2017) (O'Malley dissent) (expressing frustration that it is "frequently impossible to delineate between a pure claim construction argument and a noninfringement argument"). The Court should decline to credit Defendants' arguments in this regard.

III. CONCLUSION

For the reasons above and in Plaintiffs' opening brief, Plaintiffs respectfully request that this Court adopt Plaintiffs' proposed claim constructions and reject Defendants' constructions.

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Respectfully submitted,

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